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No. 03-388

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

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DENNIS BATES, *et al.*,

Petitioners,

v.

DOW AGROSCIENCES, LLC,

Respondent.

On Writ Of Certiorari to the United States Court Of Appeals For The Fifth Circuit

BRIEF OF EDWIN L. JOHNSON AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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IDENTITY AND INTEREST OF *AMICUS CURIAE*

Pursuant to Rule 37 of the Rules of this Court, Edwin L. Johnson respectfully submits this brief as *amicus curiae* to urge affirmance of the judgment below.[1]

Mr. Johnson earned a Bachelor of Engineering from Yale University in 1957, a Masters in Public Administration in 1962 and a Masters in Economics in 1964, both from Harvard University.

From 1970 to 1992 Mr. Johnson worked at the United States Environmental Protection Agency ("EPA" or the "Agency"). During 1971 and 1972, Mr. Johnson served as assistant to the Assistant Administrator for Categorical Programs (the office within EPA that, at the time, had primary responsibility for regulating pesticides), and from 1972 to 1984, Mr. Johnson held senior management positions within EPA's Office of Pesticide Programs.

From 1972 to 1975, as Director of Policy and Operations for the Office of Pesticide Programs, Mr. Johnson was responsible for strategic planning for the regulation of pesticides in the United States and was a direct deputy to the Deputy Assistant Administrator for Pesticides. From 1975 to 1984, as Deputy Assistant Administrator for Pesticides (and subsequently Director of the Office of Pesticide Programs),

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[1] The parties have submitted blanket consents to the filing of *amicus curiae* briefs. Pursuant to Rule 37.6 of the Rules of this Court, Edwin L. Johnson states that no counsel for a party has written this brief in whole or in part, and that Cheminova, Inc., a registrant of registered pesticide products sold in the United States, is the only person or entity other than *amicus curiae* and its counsel that has made a monetary contribution to the preparation and submission of this brief.

Mr. Johnson directed and managed the U.S. program for the regulation of pesticides and supervised all EPA staff responsible for the registration and reregistration of pesticides. During this period, he had primary responsibility for developing EPA policies implementing the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136, *et seq.*, and he played a leading role within the Agency in developing legislative proposals pertaining to pesticide regulation. He also represented EPA's pesticide office before Congress and before state and local governments. From 1984 to 1992, Mr. Johnson held various senior management positions within EPA, including Director of the International Issues Division from 1989 to 1992, where he had responsibility for international pesticide regulation issues.

Since leaving EPA in 1992, Mr. Johnson has worked as a consultant on global environmental and regulatory issues, particularly those relating to pesticides.

As a result of his many years of experience in senior positions within EPA's pesticide program, and his related experience since then, Johnson is intimately familiar with the 1972 and 1978 amendments to FIFRA, and EPA's regulations and policies implementing those amendments. Johnson submits this *amicus curiae* brief for two principal purposes:

(1) To help the Court understand the "efficacy data waiver" provisions that Congress added to FIFRA in the 1978 amendments to the Act; and

(2) To demonstrate that petitioners and the *amici* in support of petitioners, in particular *amicus curiae* Herbert Samuel Harrison, are incorrect in asserting that, as a result of the efficacy data waiver provisions of the 1978 amendments, EPA no longer regulates the efficacy of registered pesticide products. In this regard, it is significant that during his years

as Deputy Assistant Administrator for Pesticides and Director of the Office of Pesticide Programs at EPA, Mr. Johnson directed the program office in which Herbert S. Harrison, *amicus curiae* in support of petitioners, worked.

SUMMARY OF ARGUMENT

Under FIFRA, a person seeking to register a pesticide in the United States must demonstrate to EPA that the pesticide will not cause unreasonable adverse effects on the environment when it is used as intended.[2] *See* 7 U.S.C. § 136a(c)(5)(D). Typically, in order to make such a showing, an applicant must provide EPA with a voluminous amount of health, safety, and environmental data, and often efficacy data, in support of the applicant's pesticide registration application.

In 1978, Congress enacted several amendments to FIFRA that were intended to streamline the registration process. Among the provisions added by these amendments was the efficacy data waiver, now codified at 7 U.S.C. § 136a(c)(5). The efficacy data waiver provides EPA with discretionary authority to exempt a pesticide from the requirement to submit efficacy data as part of the registration application, if EPA determines that other mechanisms for assuring product efficacy are sufficient. *Id.*

When Congress enacted the efficacy data waiver, its sole purpose was to facilitate the process of registering pesticide

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[2] For purposes of this provision, the term "unreasonable adverse effects on the environment" is defined, in relevant part, to mean: "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb).

products, through a more efficient use of EPA and applicant resources; Congress did not intend for the efficacy data waiver to modify the express preemption provisions contained in a separate section of FIFRA, 7 U.S.C. § 136v. Moreover, even with the efficacy data waiver in place, FIFRA continues to provide EPA with robust authority to regulate the efficacy of registered pesticide products, notwithstanding the contrary suggestions of petitioners and the *amici* in support of petitioners.

ARGUMENT

I. CONGRESS ENACTED THE EFFICACY DATA WAIVER TO MAKE REGISTRATION AND REREGISTRATION MORE EFFICIENT; IT DID NOT INTEND TO MODIFY THE EXPRESS PREEMPTION PROVISIONS OF FIFRA SECTION 136v(b).

In 1972 Congress fundamentally restructured the way pesticides are regulated in the United States when it passed the Federal Environmental Pesticide Control Act ("FEPCA"), Pub. L. 92-516, 86 Stat. 973 (1972). This 1972 law made extensive changes to FIFRA and, in so doing, transformed FIFRA "from a labeling law into a comprehensive regulatory statute that will henceforth more carefully control the manufacture, distribution, and use of pesticides." H.R. Rep. No. 92-511, at 1 (1971). *See also*, *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984). In addition to expanding the scope of the federal program for pesticide regulation, the 1972 amendments also added the express preemption provision in FIFRA § 136v(b), which provides that no State shall impose "any requirements for labeling or packaging" that differ from those required under FIFRA. 7 U.S.C. § 136v(b).

The expansion of the FIFRA regulatory program that was accomplished by the 1972 amendments placed extraordinary,

and sometimes conflicting, demands on EPA's resources. In addition, in its efforts to implement the statute, EPA discovered that some of the provisions of the 1972 amendments created obstacles to the registration process that were largely unforeseen at the time the amendments were passed. *See* H.R. Rep. No. 95-663, at 18 (1977) ("It has been evident for some time . . . that there continue to be many problems that preclude effective implementation of the major changes in the law that came into effect in 1972."). As a result, by 1977 the centerpiece of the FIFRA regulatory program, the registration and reregistration process for pesticide products, "had ground to a virtual halt." S. Rep. No. 95-334, at 3 (1977).

In order to break this regulatory logjam, EPA concluded that a legislative fix would be required. Accordingly, EPA proposed to Congress several specific amendments to FIFRA which, in the Agency's view, were "critical to ending the impasse in registration...." *Id.* at 70 (Stmt. of Douglas M. Costle, Adm'r, EPA (Apr. 27, 1977)). One of the amendments that EPA proposed was the efficacy data waiver provision. This provision, along with nearly all of the other legislative changes that had been proposed by EPA, was enacted into law as part of the 1978 amendments to FIFRA. Pub. L. 95-396, 92 Stat. 819 (1978).

The efficacy data waiver authorizes EPA to waive the requirement for applicants to supply EPA with efficacy data "up-front" in support of the registration of their products. Specifically, the waiver provides that "[i]n considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's

composition is such as to warrant proposed claims of efficacy." 7 U.S.C. § 136a(c)(5).[3]

EPA sought to include the efficacy data waiver in the 1978 FIFRA amendments for one, and only one, purpose: to streamline the registration process through a more efficient and rational allocation of Agency and applicant resources. As the Agency subsequently explained:

> The decision to pursue efficacy waiver as an Agency policy stemmed from a need to reduce the amount of resources devoted to reviewing product performance so that additional effort could be devoted to the evaluation of health and safety data, and from a desire to reduce regulatory burdens in pesticide registration.

44 Fed. Reg. 27,932, 27,938 (May 11, 1979) (interim final regulations on conditional registration). *See also* S. Rep. No. 95-334, at 73 (Stmt. of Douglas M. Costle, Adm'r, EPA (Apr. 27, 1977)) ("we feel that far too much Agency time is

[3] The statutory standard for registration is set forth in § 136a(c) of FIFRA. Under that section, EPA may register a product if the Agency determines that the following criteria are satisfied:

> (A) [the product's] composition is such as to warrant the proposed claims for it;
>
> (B) its labeling and other material required to be submitted comply with the requirements of this [Act];
>
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
>
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

7 U.S.C. § 136a(c)(5).

currently being spent in reviewing efficacy data while shortages abound in the reregistration validation areas.").

From the legislative history of the 1978 amendments, it is clear that Congress had a similar goal in mind when it passed the efficacy data waiver provision. Specifically, Congress had concluded that "[t]he expenditure of resources by the Environmental Protection Agency in reviewing efficacy data is not the best use of resources …." S. Rep. No. 95-334, at 9. By enacting the data waiver, Congress expected that it would "reduce significantly the regulatory burden in the registration process…" and at the same time "permit the EPA to shift resources from the relatively less important criteria of registration to the much more critical questions of health and safety." *Id.* at 28. "This will enhance the effectiveness of the pesticide program by reducing regulatory burdens for the basic manufacturers and by providing a larger share of the EPA resources to service their registrations." *Id.*

If Congress had intended, through the 1978 amendments, to modify the express preemption provision of § 136v(b) so as to exclude efficacy claims from the scope of FIFRA preemption, it is reasonable to expect that Congress would have done so explicitly. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) (where a statute contains an express preemption provision, "there is no need to infer congressional intent to pre-empt state laws from the substantive provisions of the legislation.") (internal quotes omitted). Of course, Congress did not make such a change to the terms of § 136v(b) in the 1978 amendments. In fact, in the 1978 amendments Congress *did* make two minor changes to the wording of the preemption provision.[4] *See* Pub. L. 95-396

[4] Specifically, the provision was changed to read as follows: "Such St[illegible] shall not impose or continue in effect any requirements for labeling *or* packaging in addition to or different from those required *under* this

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§ 22, 92 Stat. 819, 835 (1978). As Congress acknowledged at the time, with these minor language changes, "the section restates section 24(b) virtually as it now reads in FIFRA." H.R. Rep. No. 95-663 at 36 (1977). The fact that Congress essentially re-enacted the FIFRA preemption provision without making any substantive changes is compelling evidence that Congress did not intend to modify the scope of FIFRA preemption in the 1978 amendments. Similarly, there is no hint in the legislative history that Congress intended the efficacy data waiver provision to alter the scope of FIFRA preemption. Instead, the legislative history of the 1978 amendments makes abundantly clear that the efficacy data waiver was "designed to facilitate registration" by streamlining the registration process to make better use of EPA and applicant resources. H.R. Rep. 95-663, at 15 (1977). This was Congress's only intent in enacting the efficacy data waiver.

II. IMPLEMENTATION OF THE EFFICACY DATA WAIVER DID NOT ELIMINATE THE REGULATION OF PRODUCT EFFICACY UNDER FIFRA

Petitioners and the *amici* in support of petitioners are wrong in asserting that because of the efficacy data waiver "there simply is no federal regulation of pesticide efficacy." Br. for *Amicus Curiae* Herbert Samuel Harrison at 3. To the contrary, FIFRA provides EPA with robust authority to regulate efficacy, even with respect to those pesticides for

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subchapter." Pub. L. 95-396 § 22, 92 Stat. 819, 835 (1978) (emphasis added). The provision had previously read: "such State shall not impose or continue in effect any requirements for labeling *and* packaging in addition to or different from those required *pursuant to* this subchapter." Pub. L. 92-516 § 24, 86 Stat. 973 (emphasis added).

which the Agency does not require the up-front submission of efficacy data.

First, it is important to recognize that the efficacy data waiver in § 136a(c)(5) does not eliminate the need to develop efficacy data and submit such data to EPA in support of pesticide registration applications, nor does it eliminate or curtail the Agency's authority to regulate efficacy. Instead, the data waiver provision authorizes "the Administrator, *at his discretion*, to waive data requirements pertaining to efficacy, in considering an application for registration." S. Rep. No. 95-334, at 19-20 (emphasis added). In particular, Congress enacted this provision with the expectation that EPA would exercise this discretion to waive the up-front submission of efficacy data when "the Administrator found that some other procedure for assuring the efficacy of pesticide products appeared to be sufficient...." *Id.* at 20.

In its implementation of the efficacy data waiver, EPA has determined that, for certain types of pesticide products, up-front submission of efficacy data should not be required because other means of assuring efficacy are sufficient. For example, in its initial rulemaking pursuant to the efficacy data waiver provisions, EPA concluded that up-front submission of efficacy data for agricultural pesticides should not as a general matter be required, noting that:

> [t]he Agency's viewpoint concerning waiver of efficacy data requirements is in line with a general belief among persons in the pesticide industry, the U.S. Department of Agriculture and the agricultural community that the efficacy of agricultural pesticides can be effectively regulated by the marketplace (in conjunction with extension services and university research personnel).

44 Fed. Reg. 27,932, 27,938 (May 11, 1979).

However, even in those circumstances when other means of assuring efficacy (apart from up-front data submission) are initially presumed to be adequate (for example, with agricultural pesticides), EPA has repeatedly asserted that the Agency will act to *require* the submission of efficacy data if it turns out that these alternate means of assuring efficacy prove to be insufficient. *Id.* at 27,939 ("A request [for efficacy data] may be made for any product for which a pattern of inadequate performance has been reported."); *see also* 45 Fed. Reg. 72,948, 72,951 (Nov. 3, 1980) (proposed data guidelines for registration). Indeed, EPA has asserted that in *any* situation where the Agency has concerns regarding a product's performance, EPA may require the submission of efficacy data:

> [T]he Agency retains the right to require the submission of efficacy test data or other evidence, on a case-by-case basis, for any pesticide product, registered or proposed for registration, for which a lack of efficacy has been reported, for evaluation of product benefits when product risks are substantial, or when other factors exist which make submission of such data necessary or desirable to support the presumption that it is efficacious.

47 Fed. Reg. 53,192, 53,197 (Nov. 24, 1982) (proposed data submission requirements).

EPA has also made clear that even if up-front submission of efficacy data is waived for a pesticide, the registrant nevertheless is expected to develop and maintain data sufficient to demonstrate the product's efficacy. As stated in EPA's regulations implementing the efficacy data waiver:

> [*E*]*ach registrant* must ensure through testing that his products are efficacious when used in

> accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

40 C.F.R. § 158.640(b)(1) (2004).

Up-front submission of efficacy data is essentially a pre-market review mechanism that allows EPA to regulate product efficacy at the point in time when a registration application is filed for a product. However, FIFRA provides EPA with a number of other tools for regulating product efficacy, apart from this "pre-market" review. Thus, even in those instances where up-front submission of efficacy data has been waived, there are still several other statutory mechanisms that are available to EPA to regulate product efficacy.[5]

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[5] In this regard, it is worth noting that EPA regulates other aspects of pesticide products (apart from efficacy) without requiring up-front submission of data, or other forms of pre-market review. For example, registrants are permitted to "certify" the physical and chemical characteristics of their products, without submitting study reports or other data to support those certifications. *See* Office of Pesticide Programs, U.S. Envtl. Prot. Agency, Pesticide Registration (PR) Notice 98-1, "Self-Certification of Product Chemistry Data," *available at* http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf. Nevertheless, EPA clearly exercises regulatory authority over the physical and chemical make-up of pesticide products, and the Agency could initiate an enforcement action under § 136j(a)(1)(C) if the composition of a product were to differ from the product composition described to the Agency in connection with registration.

Similarly, EPA does not require registrants to submit copies of advertising or promotional materials for pre-market review by the Agency; nevertheless, EPA exercises jurisdiction over such promotional

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As an example, FIFRA prohibits the sale or distribution of pesticide products that are misbranded. 7 U.S.C. § 136j(a)(1)(E). For purposes of the statute, a product is considered to be misbranded if its labeling contains any statement regarding the product that "is false or misleading in any particular" (7 U.S.C. § 136(q)(1)(A)) or if the label accompanying the product "does not contain directions for use which are necessary for effecting the purposes for which the product is intended…"(7 U.S.C. § 136(q)(1)(F)). Thus, if the efficacy of a product is insufficient to warrant labeling statements or claims (or if the labeling is otherwise misleading with respect to efficacy), the product will be deemed misbranded. Misbranded products are subject to stop sale, use, removal or seizure orders under 7 U.S.C. § 136k, and persons selling or distributing such products are subject to civil or criminal penalties, under 7 U.S.C. § 136l.

Along similar lines, under § 136d(b) of FIFRA EPA may cancel a product's registration if the Administrator finds that: (i) the product or its labeling does not comply with the Act, or (ii) the product when used in accordance with widespread practice causes "unreasonable adverse effects on the environment…." 7 U.S.C. § 136d(b). Thus, if the composition of a registered product does not warrant the claims that are made for it, in contravention of § 136a(c)(5) (in other words, if the product or its labeling does not comply with the Act), EPA could pursue cancellation of the product's registration. *See, e.g.*, 58 Fed. Reg. 41,779, 41,785-86 (Aug 5, 1993) (notice of intent to cancel based in part upon "false and misleading claims" on product labeling). Similarly, if the

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claims, and can bring an enforcement action if such claims are inconsistent with labeling and other information submitted to EPA in connection with registration. *See* 7 U.S.C. § 136j(a)(1)(B); *see also*, 40 C.F.R. Part 168, Subpart B (2004) (entitled "Advertising").

Administrator determines that the benefits of a product (which includes the product's efficacy) are significantly outweighed by the risks of the product, the Agency could pursue cancellation on the basis of the "unreasonable adverse effects" associated with the product. *Id.* at 41,779 (notice of intent to cancel "based in part on a determination that continued sale, distribution, and use of the product would cause unreasonable adverse effects on the environment. This determination is based upon data and other information showing that this product is not efficacious when used as a sterilant in accordance with its label claims.").

As the foregoing demonstrates, FIFRA provides EPA with robust authority to exercise regulatory control over the efficacy of registered pesticide products, even in those instances where up-front submission of efficacy data is not required as part of an application for registration. As EPA has explained:

> The Agency expects and believes that registrants will ensure that their products are efficacious when used in accordance with label directions and commonly accepted pest control practices. Under the statute, the registrant still has the responsibility to insure that a product satisfies its label claims. The Agency would take corrective action on a product including, when necessary, enforcement or cancellation actions, since the registrants must still comply with the law.

47 Fed. Reg. 53,192, 53,197. Consequently, the assertion that is made by petitioners and the *amici* in support of petitioners, to the effect that there is no federal regulation of pesticide efficacy, is simply erroneous.

Moreover, the current system for regulating the efficacy of registered pesticides has worked well. Shortly after the waiver was enacted, EPA warned that if the Agency were to

obtain evidence that this "experiment in public policy" was being abused by registrants ("such as a significant increase in complaints from the agricultural community, other user groups, or the general public about ineffective products") the Agency would take appropriate steps in response, including withdrawing "any or all waivers of efficacy data requirements." 44 Fed. Reg. 27,932, 27,938 (May 11, 1979). In point of fact, because of overriding business considerations, pesticide registrants continue to conduct extensive testing to ensure that their products are safe and effective when used as directed, even if those products are exempt from the up-front submission of efficacy data.[6] The fact that EPA has not had to follow through on its threat to rescind the data waiver if it were "abused" is a good indication that the current system for regulating product efficacy has worked well.[7]

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[6] One reflection of this can be seen in the numerous studies that have shown that registered pesticides are responsible for preventing billions of dollars of crop losses in the United States each year. *See, e.g.*, Leonard P. Gianessi & Sujatha Sankula, *The Value of Herbicides in U.S. Crop Production*, National Center for Food and Agric. Pol'y (Apr. 2003), *available at* http://www.ncfap.org/benefits.htm.

[7] EPA has not acted to rescind the efficacy data waiver. In 1982 the Agency proposed to *expand* the waiver to encompass certain products intended for the control of vertebrates (such as rodents). *See* 47 Fed. Reg. 40,659 (Sep. 15, 1982). This proposal was subsequently incorporated into the data requirements applicable to conditional registrations. 48 Fed. Reg. 34,000 (Jul. 26, 1983). However, shortly thereafter, EPA abandoned the proposal because the Agency concluded that, for these types of pesticides, other means of assuring efficacy (aside from up-front data submission) would not be sufficient. *See* 49 Fed. Reg. 380, 381-82 (Jan. 4, 1984).

CONCLUSION

By enacting the efficacy data waiver provisions in § 136a(c)(5), Congress did not extinguish the regulation of pesticide product efficacy under FIFRA, nor did it otherwise limit the preemptive effect of FIFRA with respect to labeling claims for efficacy. *Amicus curiae* therefore urges this Court to uphold the judgment of the United States Court of Appeals for the Fifth Circuit.

Respectfully submitted,

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